GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1978
ANSWERED ON:21.07.2004
EFFECTIVE DRUG REGULATORY SYSTEM
Paswan Shri Sukdeo

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has any plan to make stronger and stringent laws pertaining to Drug Regulatory System in order to make authority more effective to protect public health;

(b) whether the Government is aware that due to loophole in inspection mechanism, quality of drugs and to track spurious or adulterated drug is not being properly monitored;

(c) whether it is a fact that globally banned or withdrawn drugs are still being allowed to be sold in the country;

(d) whether many drugs are illegally circulating in the market without mandatory approval of concerned authority;

(e) whether the Government is also aware that cost of the medicines has down to roughly 1/10th of its cost in West, but in India it is on increasing side; and

(f) if so, the details thereof and the measures proposed to be taken in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a): The Drugs and Cosmetics (Amendment)Bill, 2003 to amend the Drugs and Cosmetics Act, 1940 was introduced on 22.12.2003, in the 13th session of Lok Sabha to enhance penalties for violation of the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder. The salient amendments proposed under the Bill are given below:-

1.Enhance the punishments relating to adulterated or spurious drugs likely to cause death or grievous hurt within the meaning of Sec.320 of the Indian Penal Code; upto punishment of death or imprisonment for a term which shall not be less than 10 years but which may extend to imprisonment for life and shall also be liable to fine of one lakh rupees or upto three times the value of the goods seized, whichever is higher.

2.Penalties for subsequent offences to be enhanced upto 10 years and with fine which shall not be less than one lakh rupees.

3.Offences relating to adulterated and spurious drugs to be made non-bailable and cognizable.

4.Provision for setting up of special courts to try offences of spurious or adulterated drugs.

5.To confer powers upon police officers not below the rank or sub-inspector or other designated officer to institute prosecutions under the said Act.

6.Provision for compounding of minor offences under the Act.

The proposed amendments would make the law deterrent to the offenders involved in the manufacture or sale of adulterated or spurious drugs.The involvement of enforcing agencies like Police would help in speedy investigations to book the culprits and in controlling anti-social elements involved in such activities. Since the Bill has now lapsed, necessary action to introduce a Bill for this purpose before the Fourteenth Lok Sabha has been initiated.

(b):Under the provisions of Drugs and Cosmetics Act 1940 and rules thereunder, the responsibility to regulate the manufacture and sale of drugs and monitoring their quality rests with the State Drug Control Authorities. Due to lack of uniformly adequate infrastructure in the States, there is variation in the level of enforcement in different States. The above amendments in the Act would strengthen the hands of regulatory Authorities in checking the quality of drugs moving in the market and to track spurious and adulterated drugs.

(c):There is no uniform globally accepted system of banning of drugs. Drugs withdrawan in one country are not necessarily withdrawn in other countries. The reports of prohibition of any specific drug in a country and the reasons thereof are examined by the regulatory authorities of other countries and action for banning of the drug is taken after examining its dose and usage permitted in the country overall benefit risk ratio and its requirements in the country. For example Drugs like Cisapride and Phenyl, propanolamine are prohibited in U.S.A but are permitted to be marketed in many European countries.

(d):Under the Drugs and Cosmetics Act, 1940, it is prohibited to manufacture for sale or for distribution, or sell, or stock or exhibit, or offer for sale, or distribute any drug, except under, and in accordance with the conditions of a licence issued for such purpose.

(e) & (f): No authentic information regarding the price trends or medicines in West is available with National Pharmaceutical Pricing Authority (NPPA). As far as Indian market is concerned, in general, the prices or medicines have not gone up unreasonably. The percent change in whole sale price index (WPI) for Drugs and Medicines during the past 4 years is less as compared to that for all commodities, as given below:-

% Change in WPI over preceding year
(Source: Ministry of Commerce & Industry)

Year Particulars	2000-2001	2001-2002	2002-2003	2003-2004
Drugs & Medicines	5.85	3.48	0.71	2.55
All Commodities	7.16	3.60	3.41	5.46

Note: % Change in WPI worked out by NPPA on the basis of the data obtained from the Office of the Economic Adviser, Ministry of Commerce & Industry.